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10/621,274	07/17/2003	William Lawrence Lyons IV	62291.010401	3039

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/621,274

Applicant(s)

LYONS, WILLIAM LAWRENCE

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION*****Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "40" as included in Figures 1, 2 and 6; "28" as included in Figure 3; "28'" as included in Figure 5; "18'" as included in Figure 5; "31" as included in Figure 7; "102" as included in Figure 8; and "170" as included in Figure 11. Corrected drawing sheets, or amendment to the specification to add the reference character(s) in the description, are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because:

- a. In Figure 4, reference character "18" apparently should read --20--.
- b. In Figure 6, reference character "14" and reference character "14'" apparently designate the same element in the figure.
- c. In Figure 7, reference character "18" apparently should read --16-- or --20--.

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- d. In Figure 10, reference character "18" (each occurrence) apparently should read --16--.
- e. In Figure 11, reference character "18" apparently should read --16--.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "80" has been used to designate both a "screw top" in Figure 5 and page 11, lines 2 and 3 of the specification and a "connector tube" in Figure 6 and page 11, line 14 of the specification. Additionally, reference character "82" has been used to designate both a "canister holder" in Figure 5 and page 11, lines 2 and 7 of the specification and a "three way fitting" in Figure 6 and page 11, line 15 of the specification. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement

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drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference character(s) mentioned in the description: "33" as mentioned at page 8, lines 17, 21 and 32. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### *Specification*

5. The disclosure is objected to because of the following informalities:
- a. On page 2, line 29, "he" apparently should read --be--.
  - b. On page 3, line 22, --to-- apparently should be inserted before "separate".

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- c. On page 8, line 3, "he" apparently should read --be--.
- d. On page 10, line 28, "26'" apparently should read --26'"--.
- e. On page 10, line 29, "16'" apparently should read --16'"--.
- f. On page 11, line 11, "26'" apparently should read --26'"--.
- g. On page 11, line 15, "22'" apparently should read --22'"--.
- h. On page 12, line 4, "22'" apparently should read --22'"--.
- i. On page 12, line 5, "46'" apparently should read --46'"--.
- j. On page 12, line 10, "18" apparently should read --16--.
- k. On page 15, line 23, a period should be inserted following "herein".
- l. On page 16, line 8, --is-- apparently should be inserted before "provided".

Appropriate correction is required.

### *Claim Objections*

- 6. Claim 1 is objected to because of the following informalities: in line 2, "which can" apparently should read --adapted to--. Appropriate correction is requested.
- 7. Claim 6 is objected to because of the following informalities: in lines 2 and 3, "(a)", "(b)", "(c)" and "(d)" should be deleted as the reference characters add no patentable weight to the claim language, and reference characters "(a)", "(b)" and "(c)" have already been used in lines 11-12 of claim 1. Appropriate correction is required.

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8. Claim 7 is objected to because of the following informalities: in line 2, “(a)” and “(b)” should be deleted as the reference characters add no patentable weight to the claim language, and reference characters “(a)” and “(b)” have already been used in lines 11-12 of claim 1.

Appropriate correction is required.

9. Claim 14 is objected to because of the following informalities: in lines 2 and 3, “(a)”, “(b)”, “(c)” and “(d)” should be deleted as the reference characters add no patentable weight to the claim language, and reference characters “(a)”, “(b)” and “(c)” have already been used in lines 11-12 of claim 1. Appropriate correction is required.

10. Claim 15 is objected to because of the following informalities: in line 2, “(a)” and “(b)” should be deleted as the reference characters add no patentable weight to the claim language, and reference characters “(a)” and “(b)” have already been used in lines 11-12 of claim 1.

Appropriate correction is required.

11. Claim 18 is objected to because of the following informalities: in line 3, “may” apparently should read --is adapted to--. Appropriate correction is requested.

12. Claim 23 is objected to because of the following informalities: in line 2, “which can” apparently should read --adapted to--. Appropriate correction is requested.

13. Claim 24 is objected to because of the following informalities: in line 3, "may" apparently should read --is adapted to--. Appropriate correction is requested.

14. Claim 25 is objected to because of the following informalities: in lines 1 and 2, "(a)" and "(b)" should be deleted as the reference characters add no patentable weight to the claim language, and reference characters "(a)" and "(b)" have already been used in lines 19-20 of claim 23. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the claim recites the limitation "a mechanism for deploying the specimen retrieval bag from the housing" in line 5. Regarding claim 4, the claim recites the limitation "a mechanism for supplying gas to the duct" in lines 1-2. Regarding claim 5, the claim recites the limitation "the mechanism for supplying the gas to the duct is adapted to provide incremental inflation of the duct" in lines 1-2. Regarding claim 8, the claim recites the limitation "a mechanism for permitting gas pressure in the duct to be reduced" in lines 1-2. Regarding claim 9, the claim recites the limitation "the mechanism for permitting gas pressure in



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the duct to be reduced is adapted to provide incremental deflation of the duct” in lines 1-2.

Regarding claim 11, the claim recites the limitation “a mechanism for deflating the duct” in lines 1-2. Regarding claim 12, the claim recites the limitation “the mechanism for deflating the duct comprises a mechanism for pumping gas out of the duct” in lines 1-2. Regarding claim 13, the claim recites the limitation “the mechanism for pumping gas out of the duct is adapted to provide incremental deflation” in lines 1-2. Regarding claim 17, the claim recites the limitation “a mechanism for cinching shut the open end of the specimen retrieval bag” in lines 1-2. Regarding claim 23, the claim recites the limitations “a mechanism for inflating the duct by supplying gas to the duct” in line 15; “a mechanism for deflating the duct by permitting gas pressure in the duct to be reduced” in lines 16-17; and “a mechanism for cinching shut the open end of the specimen retrieval bag” in line 18. Regarding claim 26, the claim recites the limitation “a mechanism for pumping gas out of the duct” in lines 1-2. Regarding claim 33, the claim recites the limitation “a backflow prevention mechanism operatively connected to the string for substantially prohibiting a flow of gas back into the duct” in lines 1-3. Regarding claim 35, the claim recites the limitation “a mechanism for unfurling the specimen retrieval bag” in lines 1-2.

The preceding limitations attempt to define claim elements of the apparatus solely using functional language. The aforementioned claims do not provide any structural limitations for performing the specified functions. Applicant does not appear to be attempting to invoke 35 U.S.C. 112, sixth paragraph, since the claim limitations do not meet the first prong of the required three-prong analysis in that the aforementioned claims do not include the phrase “means for” preceding the functional language. See MPEP 2181. Since claims 1, 4, 5, 8, 9, 11-13, 17, 23, 26, 33 and 35 attempt to define claim elements solely by their specified functional language

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while failing to distinctly claim the structural limitations required to perform those specified functions, the claims are indefinite.

*Claim Rejections - 35 USC § 102*

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-20 and 23-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Heaven et al. ('754). Heaven et al. teach an isolation bag assembly that forms a specimen collection apparatus. The apparatus (see Fig. 9) includes a collapsible specimen retrieval bag having an open end which can be cinched shut to contain a specimen therein; a housing 35 for holding the specimen retrieval bag while in a collapsed state, a mechanism 36 for deploying the specimen retrieval bag from the housing; a substantially gas-tight duct 26,34 associated with the specimen retrieval bag for shaping the open end of the specimen retrieval bag, after the specimen retrieval bag is deployed from the housing, to form an aperture large enough to receive the specimen into the specimen retrieval bag; a mechanism for inflating the duct by supplying gas to the duct; a mechanism 37 for deflating the duct by permitting gas pressure in the duct to be reduced; and a mechanism 33 for cinching shut the open end of the specimen retrieval bag. The housing 35 includes a first elongated tube with two ends. The mechanism for deploying the specimen retrieval bag from the housing 36 includes a second elongated tube with an outside diameter smaller than an inside diameter of the first elongated

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tube, and the second elongated tube is capable of pushing the specimen retrieval bag out of one of the ends of the first elongated tube. The duct 26,34 is disposed between the inside surface of the specimen retrieval bag and the outside surface of the specimen retrieval bag, and forms a generally circular ring adjacent the open end of the specimen retrieval bag when gas pressure in the duct is greater than gas pressure outside the duct. The apparatus inherently includes a source of pressurized gas or liquid within an operating room in communication with a stem extending through the inner inflation/deflation tube for supplying gas to the duct in order to inflate the duct (see fluid actuating means of claim 1 of the '754 patent), since pressurized gas and liquid does not normally occur naturally within a surgical operating room environment. The source may be a hand-operated pump such as a syringe (column 9, lines 15-17) that would be capable of providing incremental inflation of the duct or, alternatively, of pumping the gas out of the duct in an incremental fashion. The mechanism 37 for deflating the duct by permitting gas pressure in the duct to be reduced is a valve formed by a gas-blocking element seatable in an interference fit with a seating surface in the interior of tube 35. The pressurized gas may be air. The mechanism 33 for cinching shut the open end of the specimen retrieval bag includes a string running at least partially through the duct, such that the string may be pulled to cinch shut the open end of the specimen retrieval bag. The stem is attached to the specimen retrieval bag at a reinforced portion of the specimen retrieval bag. The valve 37 is operatively connected to the string 33 such that the valve permits gas pressure in the duct to be reduced after the string is pulled. The valve 37 is capable of forming a backflow prevention mechanism operatively connected to the string for substantially prohibiting a flow of gas back into the duct after the string is pulled past a predetermined position during the cinching shut of the open end of the specimen retrieval bag.

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Ducts 26 form a plurality of veins extending generally away from the open end of the specimen retrieval bag and towards a closed end of the specimen retrieval bag mechanism for unfurling the specimen retrieval bag, after the specimen retrieval bag is deployed from the housing.

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heaven et al. ('754) in view of Tovey et al. ('372). Heaven et al., as discussed hereinabove, teach all of the limitations of the claims except that a knife is disposed on the end of the housing opposite that from which the specimen retrieval bag is deployed. Tovey et al. teach a specimen retrieval pouch 260 including an outer tubular housing 180 for holding the specimen retrieval pouch while in a collapsed state, where a knife 140 is disposed on the end of the housing opposite that from which the specimen retrieval pouch is deployed for cutting a drawstring thread 250 after the open end 264 of the pouch is cinched shut. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide the end of the outer tubular housing of an apparatus similar to that of Heaven et al., opposite that from which the specimen retrieval bag is deployed, with a knife in view of the teachings of Tovey et al. in order to cut the drawstring after the open end of the specimen retrieval bag has been cinched shut.

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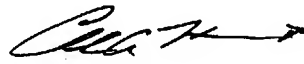
*Conclusion*

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pfeffer et al. ('289) teach an apparatus for organic specimen retrieval. Heaven et al. ('803) teach a tissue segmentation device. Heaven et al. ('633) teach a self-deploying isolation bag. Spaeth et al. teach a system for enclosing, manipulating and removing tissue through minimal access incisions. Cochran et al. ('521) teach a laparoscopy organ retrieval apparatus.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

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August 17, 2004